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before the Subcommittee on Investigations and Oversight of the House Small Business Committee

"Competitive Bidding for Durable Medical Equipment: Will Small Suppliers be able to Compete?"

October 31, 2007

Chairman Altmire, Ranking Member Gohmert, and Members of the Subcommittee, I welcome the opportunity to testify before you today on behalf of the American Podiatric Medical Association (APMA). I commend this Subcommittee for its focus on the vital issue of how competitive bidding for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) under the Medicare program will impact small businesses.

I am Dr. Ross Taubman, President Elect of the APMA and a practicing doctor of podiatric medicine. APMA is the premier professional organization representing America's Doctors of Podiatric Medicine, or "podiatrists." We represent approximately 80 percent of the podiatrists in the country, and our members provide the majority of foot care services to the Medicare population. Our mission is to advocate for the profession of podiatric medicine and surgery for the benefit of our members and the patients we serve.

Mr. Chairman, more than 60 percent of the podiatrists in this country practice in one or two person groups and would be considered small businesses. These podiatrists and practices, usually employing a very small support staff and enjoying modest annual revenues, face the same challenges confronted by all small businesses that must compete in marketplaces that are not always level playing fields. I have found during my work with APMA that many of the policy issues faced by the podiatric medical profession are, fundamentally, small business issues

that in many cases apply to other small medical practices as well. Podiatry practices and other small businesses can and do compete successfully against large businesses when the terms of that competition are fair, but success becomes difficult when arbitrary and artificial obstacles are placed in their path.

We do not believe Congress intended to construct new barriers for small businesses in recent legislation, including the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or "MMA," but the unintended consequences have been serious for podiatry practices. The Centers for Medicare & Medicaid Services (CMS) has proposed or issued regulations for the competitive acquisition of DMEPOS, as well as a requirement for DMEPOS suppliers to be accredited and to post a surety bond. These changes were designed to improve the quality of supplies furnished by large businesses to Medicare beneficiaries, but we believe the rules represent a genuine threat to the participation of small businesses in the Medicare program. Unfortunately, the difficulties associated with securing reimbursement for services from Medicare are among the most persistent challenges faced by podiatrists, and this burden falls disproportionately on small podiatric medical practices that cannot take advantage of economies of scale to spread the cost of regulatory compliance.

Physician Definition

One of the provisions of the MMA that authorizes the competitive acquisition program cites a restrictive definition of "physician" that includes only Medical Doctors (MDs) and Doctors of Osteopathy (DOs), but not Doctors of Podiatric Medicine (DPMs). This exclusion of podiatrists could potentially prevent them from performing the face-to-face examination required to prescribe DMEPOS for patients. (See addition to section 1834(a)(1) [42 U.S.C. 1395m(a)(1)] made by MMA Sec. 302(a)(2)(E)(ii) and (iv), attached.)

DPMs have been defined as physicians within their scope of practice in the Social Security Act Title XVIII definition under 1861(r) since 1967[1], and have both prescribed and furnished DMEPOS as part of patient care by Medicare. If taken literally and applied to the competitive bidding program, this provision could prevent patients from obtaining necessary DMEPOS, as

part of their care, from their podiatrists. For podiatric physicians, DMEPOS items such as walkers, canes, crutches, and walking boots are integral to the care we provide when a patient seeks our in-office services. A requirement that blocks this service would not just harm the bottom line of small podiatry practices by eliminating a relatively modest revenue stream from providing DMEPOS to patients, but it also would adversely affect the well-being of mobility-impaired patients who would be forced to travel elsewhere to obtain their needed medical device. Because this exclusion of podiatrists appears in the law, CMS has stated that Congress must make a technical correction to the MMA to resolve this issue.

APMA urges Congress to take such action this year as part of a broader Medicare package, and thereby ensure that podiatric physicians can continue providing DMEPOS to our elderly and disabled patients.[2]

Competitive Bidding

The DMEPOS competitive acquisition program presents specific challenges for small business medical practices. In theory, forcing suppliers of DME to competitively bid would seem like a good idea. However, in reality, this type of so-called "competitive" bidding can only be anti-competitive, leading to driving small medical practices and other small businesses out of the DMEPOS market entirely, leaving the market to a handful of large firms in each market. To understand this completely, one needs to understand how the vast majority of physicians, including podiatric physicians, utilize durable medical equipment in their offices.

Physician suppliers dispense small amounts of DME as an integral part of patient care. Consider a CAM walker, which is a specially designed "boot" typical of an item used when treating foot or ankle fractures. If a patient was seen in my office, I as a physician supplier would be able to immediately dispense this item to my patient, insuring stability of a fracture and providing immediate comfort to my patient. If subject to competitive bidding, I would need to make a bid to Medicare and be selected as a wining bidder to be able to continue to supply these items to my patients at the point of care. This is a completely unfair playing field from a cost basis. Since I may stock only two or three of a given item at a time in my small office, there is no way that I

can take advantage of economies of scale compared to a large supply house that purchases thousands of these items at a time. Therefore, it is impractical for a small business physician who dispenses DMEPOS as an integral part of patient care to compete in the competitive bidding process.

CMS made some concessions to small businesses in its final rule implementing the program but those modifications only benefit the small businesses that can submit a bid. The language intended to protect small business suppliers does not overcome the burden of producing a bid in the first place. In addition, under the final rule implementing the DMEPOS competitive bidding program, CMS did specify that physicians would be allowed to furnish certain competitively bid items to their own patients without submitting a bid and being selected as a contract supplier, as long as certain conditions were met. However, this special accommodation applies only to crutches, canes, walkers, folding manual wheelchairs, blood glucose monitors and infusion pumps. It would not apply to this kind of walking boot. While most DMEPOS was not included under Phase I of the competitive bidding program (for the first 10 competitive bidding areas), if they are subjected to competitive bidding in a later phase of the program you can easily see how this would likely interfere with good patient care. For a patient with a fracture, I would almost certainly find it necessary to send him or her out of my office, perhaps across town or to another county, to get a necessary DMEPOS product from a large supply house.

Mr. Chairman, not only would this be unfair to me as a small businessman, it also would not be good medical care. In a rural area, it would be even worse and the patient in all probability would need to travel even greater distances. Therefore, I urge Congress to exempt all physician suppliers that dispense DMEPOS as an integral part of their patient care from the competitive bidding process.

Accreditation

The Medicare program's new accreditation requirements for DMEPOS suppliers also impose a burden on small medical practices (See addition to section 1834(a) (42 U.S.C. 1395m(a)) made by MMA Sec. 302(a)(1), attached.) The MMA requires all DMEPOS suppliers to be accredited

by a CMS-recognized organization. This accreditation is time-consuming, expensive, and heavy on paperwork – precisely the type of barrier that large companies are well equipped to surmount, but which pose special difficulties for small businesses that cannot afford to hire full-time regulatory compliance staff. For example, I recently downloaded the supplier manual from one of the CMS-sanctioned accrediting organizations for podiatric physicians. This 128-page manual presents the administrative red tape to meet the CMS requirements, which are unrealistic for small physician supplier practices. Additionally, the cost of accreditation essentially insures that physician suppliers will no longer be suppliers of DPMPOS for their patients. Consider that podiatrists who supply DMEPOS patients receive an average of $7,000 per year from Medicare. Accreditation costs a minimum of $3,000 per office for a three-year period. It is not difficult, therefore, to understand why we find it impractical to seek accreditation just to continue dispensing these items in our offices.

Furthermore, this sort of accreditation program is unnecessary for physicians given the comprehensive medical education and stringent licensure processes to which they are already subject. Physicians are educated in institutions of higher learning that are accredited by agencies recognized by the Department of Education. They are trained in residency programs already approved by government-recognized organizations, and they are required to meet tough state standards for licensure. To apply the same accreditation standards to physicians that supply DMEPOS as an integral part of patient care that are applied to large-scale suppliers, such as WalMart or Liberty Medical, is an unnecessary, unfair, anti-competitive and costly duplication of existing rigorous processes. Therefore, the most sound public policy would be to exempt physicians from DMEPOS supplier accreditation, and deem them accredited by reason of the substantial and more stringent licensure and accreditation requirements already required of physicians. In making this point, I think it is important to emphasize that the MMA-mandated accreditation requirements will eventually affect all DMEPOS suppliers, not just those participating in the DMEPOS competitive acquisition program.

Surety Bond

An additional DMEPOS-related burden on physician suppliers arose recently when CMS proposed to require all suppliers of DMEPOS to furnish CMS with a surety bond (CMS–6006–P Medicare Program; Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies. (72 Fed. Reg. 42001, Aug. 1, 2007). The estimated annual cost of the surety bond would be $2,000. This surety bond would not be a significant expense for a large medical supply company that does hundreds of thousands of dollars of business in DMEPOS every year. However, for small businesses, including podiatry practices, the bond requirement would provide an additional disincentive to supply DMEPOS under Medicare. This would hurt small businesses and create inconveniences for Medicare patients.

CMS has acknowledged that DMEPOS suppliers with comparatively low annual charges will have little incentive to furnish the surety bond. In fact, according to CMS, "as many as 15,000 DMEPOS suppliers, or 23 percent of the 65,984 entities, and 15 percent (or 17,471) of the 116,471 individual suppliers currently enrolled in Medicare could decide to cease providing items to Medicare beneficiaries if this proposed rule is implemented." Furthermore, CMS has indicated that DMEPOS suppliers dispensing relatively small amounts of products to Medicare beneficiaries would likely cease doing so if the proposed rule is implemented. This illustrates the danger of this proposal to small businesses, including nearly all physician suppliers of DMEPOS products, and it bears highlighting: Since the average podiatric physician generates only an average of $7,000 per year in allowed annual charges, most are almost certain to stop providing DMEPOS products under Medicare if the surety bond requirement is implemented.

I also would like to point out that Congress appears to have recognized that including physicians in surety bond requirements was bad policy when it passed the Balanced Budget Act of 1997. In that legislation and the conference report accompanying it, we believe that the Congress signaled its belief that physicians should be exempted from surety bond requirements in two ways. The Act's language notes in one place that such surety bond requirements should be applied to suppliers "other than physicians or other practitioners," while the report language states unambiguously that "the conferees wish to clarify that these surety bond requirements [plural] do not apply to physicians and other health care professionals." (See pertinent section of Conference Report for BBA97 attached.)

Given the clarity of that statutory and report language, APMA does not understand why CMS proposed to include podiatrists and other physicians in the surety bond requirement. We do not believe the intent of Congress was ambiguous, and we urge this Subcommittee and others in Congress to help make it clear to CMS that physicians should be exempted from the surety bond requirement. This proposal is particularly troubling given the likelihood that it would have a deleterious effect on Medicare beneficiaries and the small businesses that serve them.

Conclusion

Implementing rules whose predictable outcome is the exclusion of thousands of small businesses from supplying DMEPOS to Medicare beneficiaries will not help the Medicare program. According to CMS, physicians and other practitioners were responsible for only 3.1 percent of DMEPOS allowed charges in 2004, and it is unclear what, if any, program improvement would be realized by imposing these requirements on physician suppliers. In conclusion, I would like to stress that the most straightforward solution to APMA's several areas of concern with the proposed DMEPOS rules, including competitive bidding, is simply to exclude physicians from the program entirely. It is nearly impossible for physicians, including podiatric physicians, to compete against much larger businesses whose sole purpose is to supply medical equipment as opposed to providing patient care.

Mr. Chairman and Members of the Subcommittee, I again thank you for providing me with the opportunity to speak today on behalf of the APMA and podiatric physicians regarding the challenges presented by Medicare's competitive bidding program, supplier accreditation, and the proposed surety bonds for DMEPOS suppliers. Attached to my written testimony are comments that we have submitted to CMS and other background documents. I respectfully submit these letters to the subcommittee and ask that they be included in the record. I will be happy to answer any questions you may have.

[1] Sec. 1861. [42 U.S.C. 1395x] Part E—Miscellaneous Provisions
DEFINITIONS OF SERVICES, INSTITUTIONS, ETC.
(r) The term "physician", when used in connection with the performance of any function or action, means (1) a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action (including a physician within the meaning of section 1101(a)(7)), (2) a doctor of dental surgery or of dental medicine who is legally authorized to practice dentistry by the State in which he performs such function and who is acting within the scope of his license when he performs such functions, (3) a doctor of podiatric medicine for the purposes of subsections (k), (m), (p)(1), and (s) of this section and sections 1814(a), 1832(a)(2)(F)(ii), and 1835 but only with respect to functions which he is legally authorized to perform as such by the State in which he performs them, (4) a doctor of optometry, but only for purposes of subsection (p)(1) with respect to the provision of items or services described in subsection (s) which he is legally authorized to perform as a doctor of optometry by the State in which he performs them, or (5) a chiropractor who is licensed as such by the State (or in a State which does not license chiropractors as such, is legally authorized to perform the services of a chiropractor in the jurisdiction in which he performs such services), and who meets uniform minimum standards promulgated by the Secretary, but only for the purpose of sections 1861(s)(1) and 1861(s)(2)(A) and only with respect to treatment by means of manual manipulation of the spine (to correct a subluxation) which he is legally authorized to perform by the State or jurisdiction in which such treatment is provided. For the purposes of section 1862(a)(4) and subject to the limitations and conditions provided in the previous sentence, such term includes a doctor of one of the arts, specified in such previous sentence, legally authorized to practice such art in the country in which the inpatient hospital services (referred to in such section 1862(a)(4)) are furnished.

[2] Proposed amendment to the Social Security Act (as amended by the MMA) to correct the Physician Definition cited and ensure Medicare patient access to DMEPOS:
(a) Section 1834(a)(1)(E)(ii) of the Social Security Act is amended by striking "(1)" from "section 1861(r)(1)"
(b) Section 1834(a)(1)(E)(iv) of the Social Security Act is amended by striking "(1)" from "section 1861(r)(1)"

H.R.1

One Hundred Eighth Congress
of the
United States of America
AT THE FIRST SESSION

Begun and held at the City of Washington on Tuesday,

the seventh day of January, two thousand and three

An Act

To amend title XVIII of the Social Security Act to provide for a voluntary program for prescription drug coverage under the Medicare Program, to modernize the Medicare Program, to amend the Internal Revenue Code of 1986 to allow a deduction to individuals for amounts contributed to health savings security accounts and health savings accounts, to provide for the disposition of unused health benefits in cafeteria plans and flexible spending arrangements, and for other purposes.

SEC. 302. PAYMENT FOR DURABLE MEDICAL EQUIPMENT; COMPETITIVE ACQUISITION OF CERTAIN ITEMS AND SERVICES.

(a) QUALITY ENHANCEMENT AND FRAUD REDUCTION-

(1) ESTABLISHMENT OF QUALITY STANDARDS AND ACCREDITATION REQUIREMENTS FOR DURABLE MEDICAL EQUIPMENT SUPPLIERS- Section 1834(a) (42 U.S.C. 1395m(a)) is amended--

(A) by transferring paragraph (17), as added by section 4551(c)(1) of the Balanced Budget Act of 1997 (111 Stat. 458), to the end of such section and redesignating such paragraph as paragraph (19); and

(B) by adding at the end the following new paragraph:

`(20) IDENTIFICATION OF QUALITY STANDARDS-

`(A) IN GENERAL- Subject to subparagraph (C), the Secretary shall establish and implement quality standards for suppliers of items and services described in subparagraph (D) to be applied by recognized independent accreditation organizations

(as designated under subparagraph (B)) and with which such suppliers shall be required to comply in order to--

`(i) furnish any such item or service for which payment is made under this part; and

`(ii) receive or retain a provider or supplier number used to submit claims for reimbursement for any such item or service for which payment may be made under this title.

`(B) DESIGNATION OF INDEPENDENT ACCREDITATION ORGANIZATIONS- Not later than the date that is 1 year after the date on which the Secretary implements the quality standards under subparagraph (A), notwithstanding section 1865(b), the Secretary shall designate and approve one or more independent accreditation organizations for purposes of such subparagraph.

`(C) QUALITY STANDARDS- The quality standards described in subparagraph (A) may not be less stringent than the quality standards that would otherwise apply if this paragraph did not apply and shall include consumer services standards.

`(D) ITEMS AND SERVICES DESCRIBED- The items and services described in this subparagraph are the following items and services, as the Secretary determines appropriate:

`(i) Covered items (as defined in paragraph (13)) for which payment may otherwise be made under this subsection.

`(ii) Prosthetic devices and orthotics and prosthetics described in section 1834(h)(4).

`(iii) Items and services described in section 1842(s)(2).

`(E) IMPLEMENTATION- The Secretary may establish by program instruction or otherwise the quality standards under this paragraph, after consultation with representatives of relevant parties. Such standards shall be applied prospectively and shall be published on the Internet website of the Centers for Medicare & Medicaid Services.'.

(2) ESTABLISHMENT OF CLINICAL CONDITIONS OF COVERAGE STANDARDS FOR ITEMS OF DURABLE MEDICAL EQUIPMENT- Section 1834(a)(1) (42 U.S.C.

1395m(a)(1)) is amended by adding at the end the following new subparagraph:

`(E) CLINICAL CONDITIONS FOR COVERAGE-

`(i) IN GENERAL- The Secretary shall establish standards for clinical conditions for payment for covered items under this subsection.

`(ii) REQUIREMENTS- The standards established under clause (i) shall include the specification of types or classes of covered items that require, as a condition of payment under this subsection, a face-to-face examination of the individual by a physician (as defined in section 1861(r)(1)), a physician assistant, nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1861(aa)(5)) and a prescription for the item.

`(iii) PRIORITY OF ESTABLISHMENT OF STANDARDS- In establishing the standards under this subparagraph, the Secretary shall first establish standards for those covered items for which the Secretary determines there has been a proliferation of use, consistent findings of charges for covered items that are not delivered, or consistent findings of falsification of documentation to provide for payment of such covered items under this part.

`(iv) STANDARDS FOR POWER WHEELCHAIRS- Effective on the date of the enactment of this subparagraph, in the case of a covered item consisting of a motorized or power wheelchair for an individual, payment may not be made for such covered item unless a physician (as defined in section 1861(r)(1)), a physician assistant, nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1861(aa)(5)) has conducted a face-to-face examination of the individual and written a prescription for the item.

`(v) LIMITATION ON PAYMENT FOR COVERED ITEMS- Payment may not be made for a covered item under this subsection unless the item meets any standards established under

this subparagraph for clinical condition of coverage.'.

(b) COMPETITIVE ACQUISITION-

(1) IN GENERAL- Section 1847 (42 U.S.C. 1395w-3) is amended to read as follows:

`COMPETITIVE ACQUISITION OF CERTAIN ITEMS AND SERVICES

`SEC. 1847. (a) ESTABLISHMENT OF COMPETITIVE ACQUISITION PROGRAMS-

`(1) IMPLEMENTATION OF PROGRAMS-

`(A) IN GENERAL- The Secretary shall establish and implement programs under which competitive acquisition areas are established throughout the United States for contract award purposes for the furnishing under this part of competitively priced items and services (described in paragraph (2)) for which payment is made under this part. Such areas may differ for different items and services.

`(B) PHASED-IN IMPLEMENTATION- The programs--

`(i) shall be phased in among competitive acquisition areas in a manner so that the competition under the programs occurs in--

`(I) 10 of the largest metropolitan statistical areas in 2007;

`(II) 80 of the largest metropolitan statistical areas in 2009; and

`(III) additional areas after 2009; and

`(ii) may be phased in first among the highest cost and highest volume items and services or those items and services that the Secretary determines have the largest savings potential.

`(C) WAIVER OF CERTAIN PROVISIONS- In carrying out the programs, the Secretary may waive such provisions of the Federal Acquisition Regulation as are necessary for the efficient implementation of this section, other than provisions relating to confidentiality of information and such other provisions as the Secretary determines appropriate.

`(2) ITEMS AND SERVICES DESCRIBED- The items and services referred to in paragraph (1) are the following:

`(A) DURABLE MEDICAL EQUIPMENT AND MEDICAL SUPPLIES- Covered items (as defined in section 1834(a)(13)) for which payment would otherwise be made under section 1834(a), including items used in infusion and drugs (other than inhalation drugs) and supplies used in conjunction with durable medical equipment, but excluding class III devices under the Federal Food, Drug, and Cosmetic Act.

`(B) OTHER EQUIPMENT AND SUPPLIES- Items and services described in section 1842(s)(2)(D), other than parenteral nutrients, equipment, and supplies.

`(C) OFF-THE-SHELF ORTHOTICS- Orthotics described in section 1861(s)(9) for which payment would otherwise be made under section 1834(h) which require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual.

`(3) EXCEPTION AUTHORITY- In carrying out the programs under this section, the Secretary may exempt--

`(A) rural areas and areas with low population density within urban areas that are not competitive, unless there is a significant national market through mail order for a particular item or service; and

`(B) items and services for which the application of competitive acquisition is not likely to result in significant savings.

`(4) SPECIAL RULE FOR CERTAIN RENTED ITEMS OF DURABLE MEDICAL EQUIPMENT AND OXYGEN- In the case of a covered item for which payment is made on a rental basis under section 1834(a) and in the case of payment for oxygen under section 1834(a)(5), the Secretary shall establish a process by which rental agreements for the covered items and supply arrangements with oxygen suppliers entered into before the application of the competitive acquisition program under this section for the item may be continued notwithstanding this section. In the case of any such continuation, the supplier involved shall provide for appropriate servicing and replacement, as required under section 1834(a).

`(5) PHYSICIAN AUTHORIZATION-

`(A) IN GENERAL- With respect to items or services included within a particular HCPCS code, the Secretary may establish a process for certain items

and services under which a physician may prescribe a particular brand or mode of delivery of an item or service within such code if the physician determines that use of the particular item or service would avoid an adverse medical outcome on the individual, as determined by the Secretary.

`(B) NO EFFECT ON PAYMENT AMOUNT- A prescription under subparagraph (A) shall not affect the amount of payment otherwise applicable for the item or service under the code involved.

`(6) APPLICATION- For each competitive acquisition area in which the program is implemented under this subsection with respect to items and services, the payment basis determined under the competition conducted under subsection (b) shall be substituted for the payment basis otherwise applied under section 1834(a), section 1834(h), or section 1842(s), as appropriate.

`(b) PROGRAM REQUIREMENTS-

`(1) IN GENERAL- The Secretary shall conduct a competition among entities supplying items and services described in subsection (a)(2) for each competitive acquisition area in which the program is implemented under subsection (a) with respect to such items and services.

`(2) CONDITIONS FOR AWARDING CONTRACT-

`(A) IN GENERAL- The Secretary may not award a contract to any entity under the competition conducted in an competitive acquisition area pursuant to paragraph (1) to furnish such items or services unless the Secretary finds all of the following:

`(i) The entity meets applicable quality standards specified by the Secretary under section 1834(a)(20).

`(ii) The entity meets applicable financial standards specified by the Secretary, taking into account the needs of small providers.

`(iii) The total amounts to be paid to contractors in a competitive acquisition area are expected to be less than the total amounts that would otherwise be paid.

`(iv) Access of individuals to a choice of multiple suppliers in the area is maintained.

`(B) TIMELY IMPLEMENTATION OF PROGRAM- Any delay in the implementation of quality standards under section 1834(a)(20) or delay in the receipt of advice from the program oversight committee established under subsection (c) shall not delay the implementation of the competitive acquisition program under this section.

`(3) CONTENTS OF CONTRACT-

`(A) IN GENERAL- A contract entered into with an entity under the competition conducted pursuant to paragraph (1) is subject to terms and conditions that the Secretary may specify.

`(B) TERM OF CONTRACTS- The Secretary shall recompete contracts under this section not less often than once every 3 years.

`(4) LIMIT ON NUMBER OF CONTRACTORS-

`(A) IN GENERAL- The Secretary may limit the number of contractors in a competitive acquisition area to the number needed to meet projected demand for items and services covered under the contracts. In awarding contracts, the Secretary shall take into account the ability of bidding entities to furnish items or services in sufficient quantities to meet the anticipated needs of individuals for such items or services in the geographic area covered under the contract on a timely basis.

`(B) MULTIPLE WINNERS- The Secretary shall award contracts to multiple entities submitting bids in each area for an item or service.

`(5) PAYMENT-

`(A) IN GENERAL- Payment under this part for competitively priced items and services described in subsection (a)(2) shall be based on bids submitted and accepted under this section for such items and services. Based on such bids the Secretary shall determine a single payment amount for each item or service in each competitive acquisition area.

`(B) REDUCED BENEFICIARY COST-SHARING-

`(i) APPLICATION OF COINSURANCE- Payment under this section for items and services shall be in an amount equal to 80 percent of the payment basis described in subparagraph (A).

`(ii) APPLICATION OF DEDUCTIBLE- Before applying clause (i), the individual shall be

required to meet the deductible described in section 1833(b).

`(C) PAYMENT ON ASSIGNMENT-RELATED BASIS- Payment for any item or service furnished by the entity may only be made under this section on an assignment-related basis.

`(D) CONSTRUCTION- Nothing in this section shall be construed as precluding the use of an advanced beneficiary notice with respect to a competitively priced item and service.

`(6) PARTICIPATING CONTRACTORS-

`(A) IN GENERAL- Except as provided in subsection (a)(4), payment shall not be made for items and services described in subsection (a)(2) furnished by a contractor and for which competition is conducted under this section unless--

`(i) the contractor has submitted a bid for such items and services under this section; and

`(ii) the Secretary has awarded a contract to the contractor for such items and services under this section.

`(B) BID DEFINED- In this section, the term `bid' means an offer to furnish an item or service for a particular price and time period that includes, where appropriate, any services that are attendant to the furnishing of the item or service.

`(C) RULES FOR MERGERS AND ACQUISITIONS- In applying subparagraph (A) to a contractor, the contractor shall include a successor entity in the case of a merger or acquisition, if the successor entity assumes such contract along with any liabilities that may have occurred thereunder.

`(D) PROTECTION OF SMALL SUPPLIERS- In developing procedures relating to bids and the awarding of contracts under this section, the Secretary shall take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in the program under this section.

`(7) CONSIDERATION IN DETERMINING CATEGORIES FOR BIDS- The Secretary may consider the clinical efficiency and value of specific items within codes, including whether some items have a greater therapeutic advantage to individuals.

`(8) AUTHORITY TO CONTRACT FOR EDUCATION, MONITORING, OUTREACH, AND COMPLAINT SERVICES- The Secretary may enter into contracts with appropriate entities to address complaints from individuals who receive items and services from an entity with a contract under this section and to conduct appropriate education of and outreach to such individuals and monitoring quality of services with respect to the program.

`(9) AUTHORITY TO CONTRACT FOR IMPLEMENTATION- The Secretary may contract with appropriate entities to implement the competitive bidding program under this section.

`(10) NO ADMINISTRATIVE OR JUDICIAL REVIEW- There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of--

`(A) the establishment of payment amounts under paragraph (5);

`(B) the awarding of contracts under this section;

`(C) the designation of competitive acquisition areas under subsection (a)(1)(A);

`(D) the phased-in implementation under subsection (a)(1)(B);

`(E) the selection of items and services for competitive acquisition under subsection (a)(2); or

`(F) the bidding structure and number of contractors selected under this section.

`(c) PROGRAM ADVISORY AND OVERSIGHT COMMITTEE-

`(1) ESTABLISHMENT- The Secretary shall establish a Program Advisory and Oversight Committee (hereinafter in this section referred to as the `Committee').

`(2) MEMBERSHIP; TERMS- The Committee shall consist of such members as the Secretary may appoint who shall serve for such term as the Secretary may specify.

`(3) DUTIES-

`(A) ADVICE- The Committee shall provide advice to the Secretary with respect to the following functions:

`(i) The implementation of the program under this section.

`(ii) The establishment of financial standards for purposes of subsection (b)(2)(A)(ii).

`(iii) The establishment of requirements for collection of data for the efficient management of the program.

`(iv) The development of proposals for efficient interaction among manufacturers, providers of services, suppliers (as defined in section 1861(d)), and individuals.

`(v) The establishment of quality standards under section 1834(a)(20).

`(B) ADDITIONAL DUTIES- The Committee shall perform such additional functions to assist the Secretary in carrying out this section as the Secretary may specify.

`(4) INAPPLICABILITY OF FACA- The provisions of the Federal Advisory Committee Act (5 U.S.C. App.) shall not apply.

`(5) TERMINATION- The Committee shall terminate on December 31, 2009.

`(d) REPORT- Not later than July 1, 2009, the Secretary shall submit to Congress a report on the programs under this section. The report shall include information on savings, reductions in cost-sharing, access to and quality of items and services, and satisfaction of individuals.

`(e) DEMONSTRATION PROJECT FOR CLINICAL LABORATORY SERVICES-

`(1) IN GENERAL- The Secretary shall conduct a demonstration project on the application of competitive acquisition under this section to clinical diagnostic laboratory tests--

`(A) for which payment would otherwise be made under section 1833(h) (other than for pap smear laboratory tests under paragraph (7) of such section) or section 1834(d)(1) (relating to colorectal cancer screening tests); and

`(B) which are furnished by entities that did not have a face-to-face encounter with the individual.

`(2) TERMS AND CONDITIONS-

`(A) IN GENERAL- Except as provided in subparagraph (B), such project shall be under the same conditions as are applicable to items and services described in subsection (a)(2), excluding subsection (b)(5)(B) and other conditions as the Secretary determines to be appropriate.

`(B) APPLICATION OF CLIA QUALITY STANDARDS- The quality standards established by the Secretary under section 353 of the Public Health Service Act for clinical diagnostic laboratory tests shall apply to such

tests under the demonstration project under this section in lieu of quality standards described in subsection (b)(2)(A)(i).

`(3) REPORT- The Secretary shall submit to Congress--

`(A) an initial report on the project not later than December 31, 2005; and

`(B) such progress and final reports on the project after such date as the Secretary determines appropriate.'.

(2) CONFORMING AMENDMENTS- Section 1833(a)(1) (42 U.S.C. 1395l(a)(1)) is amended--

(A) by striking `and (U)' and inserting `(U)';

(B) by inserting before the semicolon at the end the following: `, and (V) notwithstanding subparagraphs (I) (relating to durable medical equipment), (M) (relating to prosthetic devices and orthotics and prosthetics), and (Q) (relating to 1842(s) items), with respect to competitively priced items and services (described in section 1847(a)(2)) that are furnished in a competitive area, the amounts paid shall be the amounts described in section 1847(b)(5)'; and

(C) in clause (D)--

(i) by striking `or (ii)' and inserting `(ii)'; and

(ii) by adding at the end the following: `or (iii) on the basis of a rate established under a demonstration project under section 1847(e), the amount paid shall be equal to 100 percent of such rate,'.

(3) GAO REPORT ON IMPACT OF COMPETITIVE ACQUISITION ON SUPPLIERS-

(A) STUDY- The Comptroller General of the United States shall conduct a study on the impact of competitive acquisition of durable medical equipment under section 1847 of the Social Security Act, as amended by paragraph (1), on suppliers and manufacturers of such equipment and on patients. Such study shall specifically examine the impact of such competitive acquisition on access to, and quality of, such equipment and service related to such equipment.

(B) REPORT- Not later than January 1, 2009, the Comptroller General shall submit to Congress a report on the study conducted under subparagraph

(A) and shall include in the report such recommendations as the Comptroller General determines appropriate.

(c) TRANSITIONAL FREEZE-

(1) DME-

(A) IN GENERAL- Section 1834(a)(14) (42 U.S.C. 1395m(a)(14)) is amended--

(i) in subparagraph (E), by striking `and' at the end;

(ii) in subparagraph (F)--

(I) by striking `a subsequent year' and inserting `2003'; and

(II) by striking `the previous year.' and inserting `2002;'; and

(iii) by adding at the end the following new subparagraphs:

`(G) for 2004 through 2006--

`(i) subject to clause (ii), in the case of class III medical devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(c)(1)(C)), the percentage increase described in subparagraph (B) for the year involved; and

`(ii) in the case of covered items not described in clause (i), 0 percentage points;

`(H) for 2007--

`(i) subject to clause (ii), in the case of class III medical devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(c)(1)(C)), the percentage change determined by the Secretary to be appropriate taking into account recommendations contained in the report of the Comptroller General of the United States under section 302(c)(1)(B) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003; and

`(ii) in the case of covered items not described in clause (i), 0 percentage points; and

`(I) for 2008--

`(i) subject to clause (ii), in the case of class III medical devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(c)(1)(C)), the

percentage increase described in subparagraph (B) (as applied to the payment amount for 2007 determined after the application of the percentage change under subparagraph (H)(i)); and

`(ii) in the case of covered items not described in clause (i), 0 percentage points; and

`(J) for a subsequent year, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June of the previous year.'.

(B) GAO REPORT ON CLASS III MEDICAL DEVICES- Not later than March 1, 2006, the Comptroller General of the United States shall submit to Congress, and transmit to the Secretary, a report containing recommendations on the appropriate update percentage under section 1834(a)(14) of the Social Security Act (42 U.S.C. 1395m(a)(14)) for class III medical devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(a)(1)(C)) furnished to medicare beneficiaries during 2007 and 2008.

(2) PAYMENT RULE FOR SPECIFIED ITEMS- Section 1834(a) (42 U.S.C. 1395m(a)), as amended by subsection (a), is further amended by adding at the end the following new paragraph:

`(21) SPECIAL PAYMENT RULE FOR SPECIFIED ITEMS AND SUPPLIES-

`(A) IN GENERAL- Notwithstanding the preceding provisions of this subsection, for specified items and supplies (described in subparagraph (B)) furnished during 2005, the payment amount otherwise determined under this subsection for such specified items and supplies shall be reduced by the percentage difference between--

`(i) the amount of payment otherwise determined for the specified item or supply under this subsection for 2002, and

`(ii) the amount of payment for the specified item or supply under chapter 89 of title 5, United States Code, as identified in the column entitled `Median FEHP Price' in the table entitled `SUMMARY OF MEDICARE PRICES COMPARED TO VA, MEDICAID, RETAIL, AND

FEHP PRICES FOR 16 ITEMS' included in the Testimony of the Inspector General before the Senate Committee on Appropriations, June 12, 2002, or any subsequent report by the Inspector General.

`(B) SPECIFIED ITEM OR SUPPLY DESCRIBED- For purposes of subparagraph (A), a specified item or supply means oxygen and oxygen equipment, standard wheelchairs (including standard power wheelchairs), nebulizers, diabetic supplies consisting of lancets and testing strips, hospital beds, and air mattresses, but only if the HCPCS code for the item or supply is identified in a table referred to in subparagraph (A)(ii).

`(C) APPLICATION OF UPDATE TO SPECIAL PAYMENT AMOUNT- The covered item update under paragraph (14) for specified items and supplies for 2006 and each subsequent year shall be applied to the payment amount under subparagraph (A) unless payment is made for such items and supplies under section 1847.'.

(3) PROSTHETIC DEVICES AND ORTHOTICS AND PROSTHETICS- Section 1834(h)(4)(A) (42 U.S.C. 1395m(h)(4)(A)) is amended--

(A) in clause (vii), by striking `and' at the end;

(B) in clause (viii), by striking `a subsequent year' and inserting `2003'; and

(C) by adding at the end the following new clauses:

`(ix) for 2004, 2005, and 2006, 0 percent; and

`(x) for a subsequent year, the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year;'.

(d) CONFORMING AMENDMENTS-

(1) DURABLE MEDICAL EQUIPMENT; LIMITATION OF INHERENT REASONABLENESS AUTHORITY- Section 1834(a) (42 U.S.C. 1395m(a)) is amended--

(A) in paragraph (1)(B), by striking `The payment basis' and inserting `Subject to subparagraph (F)(i), the payment basis';

(B) in paragraph (1)(C), by striking `This subsection' and inserting `Subject to subparagraph (F)(ii), this subsection';

(C) by adding at the end of paragraph (1) the following new subparagraph:

`(F) APPLICATION OF COMPETITIVE ACQUISITION; LIMITATION OF INHERENT REASONABLENESS AUTHORITY- In the case of covered items furnished on or after January 1, 2009, that are included in a competitive acquisition program in a competitive acquisition area under section 1847(a)--

`(i) the payment basis under this subsection for such items and services furnished in such area shall be the payment basis determined under such competitive acquisition program; and

`(ii) the Secretary may use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise recognized under subparagraph (B)(ii) for an area that is not a competitive acquisition area under section 1847 and in the case of such adjustment, paragraph (10)(B) shall not be applied.'; and

(D) in paragraph (10)(B), by inserting `in an area and with respect to covered items and services for which the Secretary does not make a payment amount adjustment under paragraph (1)(F)' after `under this subsection'.

(2) OFF-THE-SHELF ORTHOTICS; LIMITATION OF INHERENT REASONABLENESS AUTHORITY- Section 1834(h) (42 U.S.C. 1395m(h)) is amended--

(A) in paragraph (1)(B), by striking `and (E)' and inserting `, (E), and (H)(i)';

(B) in paragraph (1)(D), by striking `This subsection' and inserting `Subject to subparagraph (H)(ii), this subsection'; and

(C) by adding at the end of paragraph (1) the following new subparagraph:

`(H) APPLICATION OF COMPETITIVE ACQUISITION TO ORTHOTICS; LIMITATION OF INHERENT REASONABLENESS AUTHORITY- In the case of orthotics described in paragraph (2)(C) of section 1847(a) furnished on or after January 1, 2009, that are included in a competitive acquisition program in a competitive acquisition area under such section--

`(i) the payment basis under this subsection for such orthotics furnished in such area shall be the payment basis determined under such competitive acquisition program; and

`(ii) the Secretary may use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise recognized under subparagraph (B)(ii) for an area that is not a competitive acquisition area under section 1847, and in the case of such adjustment, paragraphs (8) and (9) of section 1842(b) shall not be applied.'.

(3) OTHER ITEMS AND SERVICES; LIMITATION OF INHERENT REASONABLENESS AUTHORITY- Section 1842(s) (42 U.S.C. 1395u(s)) is amended--

(A) in the first sentence of paragraph (1), by striking `The Secretary' and inserting `Subject to paragraph (3), the Secretary'; and

(B) by adding at the end the following new paragraph:

`(3) In the case of items and services described in paragraph (2)(D) that are included in a competitive acquisition program in a competitive acquisition area under section 1847(a)--

`(A) the payment basis under this subsection for such items and services furnished in such area shall be the payment basis determined under such competitive acquisition program; and

`(B) the Secretary may use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise applicable under paragraph (1) for an area that is not a competitive acquisition area under section 1847, and in the case of such adjustment, paragraphs (8) and (9) of section 1842(b) shall not be applied.'.

(e) REPORT ON ACTIVITIES OF SUPPLIERS- The Inspector General of the Department of Health and Human Services shall conduct a study to determine the extent to which (if any) suppliers of covered items of durable medical equipment that are subject to the competitive acquisition program under section 1847 of the Social Security Act, as amended by subsection (a), are soliciting physicians to prescribe certain brands or modes of delivery of covered items based on profitability. Not later than

July 1, 2009, the Inspector General shall submit to Congress a report on such study.

Balanced Budget Act of 1997 (Enrolled as Agreed to or Passed by Both House and Senate)

SEC. 4312. DISCLOSURE OF INFORMATION AND SURETY BONDS.

(a) DISCLOSURE OF INFORMATION AND SURETY BOND REQUIREMENT FOR SUPPLIERS OF DURABLE MEDICAL EQUIPMENT- Section 1834(a) (42 U.S.C. 1395m(a)) is amended by inserting after paragraph (15) the following new paragraph:

`(16) DISCLOSURE OF INFORMATION AND SURETY BOND- The Secretary shall not provide for the issuance (or renewal) of a provider number for a supplier of durable medical equipment, for purposes of payment under this part for durable medical equipment furnished by the supplier, unless the supplier provides the Secretary on a continuing basis--

`(A) with--

`(i) full and complete information as to the identity of each person with an ownership or control interest (as defined in section 1124(a)(3)) in the supplier or in any subcontractor (as defined by the Secretary in regulations) in which the supplier directly or indirectly has a 5 percent or more ownership interest; and

`(ii) to the extent determined to be feasible under regulations of the Secretary, the name of any disclosing entity (as defined in section 1124(a)(2)) with respect to which a person with such an ownership or control interest in the supplier is a person with such an ownership or control interest in the disclosing entity; and

`(B) with a surety bond in a form specified by the Secretary and in an amount that is not less than $50,000.

The Secretary may waive the requirement of a bond under subparagraph (B) in the case of a supplier that provides a comparable surety bond under State law.'.

(b) SURETY BOND REQUIREMENT FOR HOME HEALTH AGENCIES-

(1) IN GENERAL- Section 1861(o) (42 U.S.C. 1395x(o)) is amended--

(A) in paragraph (6), by striking `and' at the end;

(B) by redesignating paragraph (7) as paragraph (8);

(C) by inserting after paragraph (6) the following new paragraph:

`(7) provides the Secretary on a continuing basis with a surety bond in a form specified by the Secretary and in an amount that is not less than $50,000; and'; and

(D) by adding at the end the following: `The Secretary may waive the requirement of a surety bond under paragraph (7) in the case of an agency or organization that provides a comparable surety bond under State law.'.

(2) CONFORMING AMENDMENTS- Section 1861(v)(1)(H) (42 U.S.C. 1395x(v)(1)(H)) is amended--

(A) in clause (i), by striking `the financial security requirement described in subsection (o)(7)' and inserting `the surety bond requirement described in subsection (o)(7) and the financial security requirement described in subsection (o)(8)'; and

(B) in clause (ii), by striking `the financial security requirement described in subsection (o)(7) applies' and inserting `the surety bond requirement described in subsection (o)(7) and the financial security requirement described in subsection (o)(8) apply'.

(3) REFERENCE TO CURRENT DISCLOSURE REQUIREMENT- For additional provisions requiring home health agencies to disclose information on ownership and control interests, see section 1124 of the Social Security Act (42 U.S.C. 1320a-3).

(c) AUTHORIZING APPLICATION OF DISCLOSURE AND SURETY BOND REQUIREMENTS TO OTHER HEALTH CARE PROVIDERS- Section 1834(a)(16) (42 U.S.C. 1395m(a)(16)), as added by subsection (a), is amended by adding at the end the following: `The Secretary, at the Secretary's discretion, may impose the requirements of the first sentence with respect to some or all providers of items or services under part A or some or all suppliers or other persons (other than physicians or other practitioners, as defined in section 1842(b)(18)(C)) who furnish items or services under this part.'.

(d) APPLICATION TO COMPREHENSIVE OUTPATIENT REHABILITATION FACILITIES (CORFS)- Section 1861(cc)(2) (42 U.S.C. 1395x(cc)(2)) is amended--

(1) in subparagraph (H), by striking `and' at the end;

(2) by redesignating subparagraph (I) as subparagraph (J);

(3) by inserting after subparagraph (H) the following new subparagraph:

`(I) provides the Secretary on a continuing basis with a surety bond in a form specified by the Secretary and in an amount that is not less than $50,000; and'; and

(4) by adding at the end the following flush sentence:

`The Secretary may waive the requirement of a surety bond under subparagraph (I) in the case of a facility that provides a comparable surety bond under State law.'.

(e) APPLICATION TO REHABILITATION AGENCIES- Section 1861(p) (42 U.S.C. 1395x(p)) is amended--

(1) in paragraph (4)(A)(v), by inserting after `as the Secretary may find necessary,' the following: `and provides the Secretary on a continuing basis with a surety bond in a form specified by the Secretary and in an amount that is not less than $50,000,', and

(2) by adding at the end the following: `The Secretary may waive the requirement of a surety bond under paragraph (4)(A)(v) in the case of a clinic or agency that provides a comparable surety bond under State law.'.

(f) EFFECTIVE DATES-

(1) SUPPLIERS OF DURABLE MEDICAL EQUIPMENT- The amendment made by subsection (a) shall apply to suppliers of durable medical equipment with respect to such equipment furnished on or after January 1, 1998.

(2) HOME HEALTH AGENCIES- The amendments made by subsection (b) shall apply to home health agencies with respect to services furnished on or after January 1, 1998. The Secretary of Health and Human Services shall modify participation agreements under section 1866(a)(1) of the Social Security Act (42 U.S.C. 1395cc(a)(1)) with respect to home health agencies to provide for implementation of such amendments on a timely basis.

(3) OTHER AMENDMENTS- The amendments made by subsections (c) through (e) shall take effect on the date of the enactment of this Act and may be applied with respect to items and services furnished on or after January 1, 1998.

105TH CONGRESS
1st Session
REPORT 105–217

BALANCED BUDGET ACT OF 1997
CONFERENCE REPORT
TO ACCOMPANY
H.R. 2015

JULY 30, (legislative day of JULY 29), 1997.—Ordered to be printed

DISCLOSURE OF INFORMATION AND SURETY BONDS

Section 10307 and 4307 of House bill and Section 5211 of Senate Amendment

CURRENT LAW

Section 1834(a) of the Social Security Act establishes requirements for payments under Medicare for covered items defined as durable medical equipment. Home health agencies are required, under Section 1861(o) of the Social Security Act, to meet specified conditions in order to provide health care services under Medicare, including requirements, set by the Secretary, relating to bonding or establishing of escrow accounts, as the Secretary finds necessary for the effective and efficient operation of the Medicare program.

HOUSE BILL

Section 10307. Requires that suppliers of durable medical equipment provide the Secretary with full and complete information as to persons with an ownership or control interest in the supplier, or in any subcontractor in which the supplier has a direct or indirect 5 percent or more ownership interest, other information concerning such ownership or control, and a surety bond for at least $50,000. Home health agencies, comprehensive outpatient rehabilitation facilities, and rehabilitation agencies would also be required to provide a surety bond for at least $50,000. The Secretary may impose the surety bond requirement which applies to durable medical equipment suppliers to suppliers of ambulance services and certain clinics that furnish medical and other health services (other than physicians' services). In each of these cases the Secretary could waive the surety bond requirement if the entity provides a comparable surety bond under state law.

Section 4307. Identical provision.

Effective Date. Applies with respect to items and services furnished on or after January 1, 1998.

SENATE AMENDMENT

Identical, except minor wording differences and provision that Secretary may also require a supplier of durable medical equipment to provide evidence of compliance with applicable Medicare conditions or requirements through an accreditation survey conducted by a national accreditation body.

CONFERENCE AGREEMENT

The conference agreement includes provisions in the House bill and the Senate amendment which are similar, with a modification making all surety bond requirements mandatory and eliminating the Senate amendment language regarding accreditation, and with clarifying language.

The Conferees wish to clarify that these surety bond requirements do not apply to physicians and other health care professionals.

AMERICAN PODIATRIC MEDICAL ASSOCIATION, INC.

June 29, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-1270-P: Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues, 71 Fed. Reg. 25,654, May 1, 2006

Dear Dr. McClellan:

The American Podiatric Medical Association (APMA), the national association representing more than 11,500 of America's premier podiatric physicians and surgeons, is pleased to present comments on the Centers for Medicare & Medicaid Services (CMS) proposed rule, *Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues*. The proposed rule would implement competitive bidding programs for certain covered items of DMEPOS. We believe that as proposed, the new program has the potential to interfere with patient care and will harm Medicare beneficiaries. We urge CMS to revise its proposals prior to implementation of a new competitive bidding program.

We would like to take this opportunity to express appreciation to your staff from the Chronic Care Policy Group and Division of Community Post Acute Care, who met with us on June 21 to discuss provisions of the proposed rule in greater detail. That meeting assisted us in clarifying specific issues of concern and we offer the following comments:

Submission of Bids under the Competitive Bidding Program

The proposed rule specifies that "physicians" that are also DMEPOS suppliers must submit bids and be awarded contracts in order to furnish items subject to competitive bidding in an area. It also notes that "physicians" that do not become contract suppliers must use a contract supplier to furnish competitively bid items to their Medicare patients. Further, the proposed rule states that "physicians" will not be required to furnish these items to beneficiaries who are not their patients if they choose not to function as commercial suppliers. In other words, such "physicians" would not be required to serve an entire competitive bidding area. Finally, the proposed rule has chosen to define the term "physician" by reference to 1861(r)(1) of the Social Security Act (which covers only doctors of medicine and doctors of osteopathy), rather than the more typical reference to 1861(r), which would also include doctors of

podiatric medicine. Below we outline in considerable detail our concerns about these aspects of the proposed rule. We begin by describing how podiatric physicians use certain DMEPOS products as an integral part of the services they provide to their patients, and how the new competitive bidding program could interfere with the practice of podiatric medicine.

DMEPOS Use by Podiatric Physicians

As podiatric physicians and surgeons, our members prescribe and supply DMEPOS items as an integral part of patient care. Similar to medical doctors (MDs) and doctors of osteopathy (DOs), our members are required to obtain a valid supplier number and must adhere to the existing 21 supplier standards. Our members are licensed in the state in which they practice, are subject to the same Stark requirements that apply to MDs and DOs and must satisfy all other Federal and State regulatory requirements.

According to CMS, there are more than 7,300 podiatric physicians who are DMEPOS suppliers. Our members provide medically necessary and appropriate DMEPOS items in treating Medicare beneficiaries. Examples of how podiatric physicians utilize DMEPOS in patient care include:

A patient presents complaining of foot pain and swelling after tripping on a sidewalk. The podiatric physician diagnoses multiple fractures of the metatarsals and determines that a Cam walker is necessary for immobilization of the injured foot. If that podiatrist no longer functions as a supplier, the patient will be forced to travel to another location to obtain the brace, treatment will be delayed or perhaps never implemented, and the patient will risk further injury to the foot.

Or, the podiatric physician may treat a patient with an acute ankle injury and determine that an ankle brace is necessary to stabilize the ankle and that crutches are necessary to limit weight-bearing on the injured extremity. If that podiatric physician is not a DMEPOS supplier in the new competitive acquisition program because he or she was unsuccessful in competing to bid to supply to the entire Metropolitan Statistical Area (MSA) rather than just to his patients, the patient will need to go elsewhere to obtain the medically necessary items. The patient risks converting the existing injury into one that is more severe, with greater recovery time and increased risks for complications.

Patients with conditions requiring acute care (e.g., fractures, foot or ankle injuries), must have immediate access to appropriate treatment, including DMEPOS items such as pneumatic walkers, non-pneumatic walkers, ankle braces, crutches, canes and walkers. These items need to be sized and fitted by the doctor. The patient needs to be instructed on proper use of the item, including weight-bearing activities.

If the patient is unable to acquire the item from the treating physician and must instead obtain the item from another supplier due to the new competitive acquisition program, negative consequences could

result. A delay in care could put the patient at risk for additional injury, which could result in increased costs to the Medicare program for the care of that patient.

For instance, if the patient with the foot fracture falls because she is unable to bear full weight on the injured extremity and breaks her hip as well, additional expenses will be incurred by the Medicare program. Or, a delay in receipt of necessary DMEPOS items could result in the deterioration of the patient's medical condition. A stable fracture could become unstable, thereby increasing the severity of the existing injury. A fracture that could initially be treated with a closed reduction could require an open reduction, which would increase costs to the Medicare program. At the very least, a delay in treatment could lead to increased, prolonged disability or less than desired results that may have a permanent impact on the activities of daily living (ADLs) of the patient.

For non-acute cases, the clinical judgment and expertise of the physician remain essential. The selection of a particular item, as well as its size and fit, should be based on the physician's evaluation of the patient. Instruction on the proper application or use of the item is important. The physician dispenses the item based on the pathology of the patient and can best explain why the item is necessary and how it must be used. The physician is able to check the fit of the item and can determine if the patient will be able to use it successfully. A different item may be needed than the one originally prescribed and the physician is the best person to make this determination.

If difficulty in using an item is not immediately identified by the physician and the patient receives it from a separate supplier and the fit is incorrect, the patient may ultimately not use the item or may use it improperly, all of which could contribute to the deterioration of the patient's condition and lead to increased costs to the Medicare program. Or, some patients may return to the physician's office with questions or for assistance, which would also increase costs due to the need for additional care or instruction.

Exclude All Physicians and Qualified Healthcare Practitioners From the DMEPOS Competitive Bidding Program

The APMA believes that all physicians, including podiatric physicians, as well as other qualified healthcare practitioners who utilize DMEPOS when caring for Medicare beneficiaries, should be exempted from the requirement to competitively bid to supply DMEPOS to their own patients. According to 2004 data on DMEPOS services, practitioners were responsible for 3.1% of DMEPOS allowed charges as a percent of all allowed charges while entities categorized as "suppliers" were responsible for 96.4% of those charges. Clearly, there is a vast difference in the amount of DMEPOS supplied by physicians and other practitioners compared to that supplied by traditional suppliers.

Most of our physicians supply limited quantities of DMEPOS items to Medicare beneficiaries. They do not maintain significant inventories and sometimes may have only one or two of a particular type of item available in the office. As an item is used, it is replenished. We seriously question the ability of our members or other physician or practitioner suppliers to compete against entities with the ability to purchase vast quantities of products in bulk. If individuals believe that competing against these larger entities is hopeless, many will not even try. If CMS expects physicians and other qualified practitioners to be able to successfully bid to supply items for the future, it needs to provide more details on the selection process; otherwise, individuals will be deterred from bidding before the program even starts.

Physicians and other practitioners who operate as small businesses and whose primary mission is to provide quality patient care that is medically necessary and appropriate and who use DMEPOS solely for purposes of enhancing that care will face significant administrative and financial burdens in trying to compete in this new program. To the detriment of patient care, many will decide against submitting a bid and will be excluded as suppliers. Rather than disrupt Medicare beneficiary access to care that is in their best interest and that occurs at a single point-of-service, we urge CMS to exclude all physicians recognized by Medicare, as well as other qualified healthcare practitioners from the requirement to competitively bid.

It is clear to the APMA that any financial gains made as a result of the proposed rule would be minimal whereas the potential risks to patient health would be huge. We fail to understand the logic of this proposal that would prevent doctors of podiatric medicine (DPMs) from being defined as physicians. We also are convinced that while the competitive bidding process may save the program some money in the initial phase, it will not only cost more to care for the complications of delayed and inappropriate care but will harm the patients we are committed to serve.

Exempt Items Integral to Patient Care

If CMS is uncertain whether the current statute would permit the agency to exclude physicians from competitive bidding altogether, as we recommend, we believe there is another alternative, at least during the early rounds of competitive bidding. CMS could exempt from competitive bidding items that are used as an integral part of patient care provided by physicians and other qualified healthcare practitioners. This would not only allow physicians to continue to serve their Medicare patients without undue interference, it would also provide time for CMS to consult with relevant Congressional Committees regarding the current statutory language and the possible need for amendments or clarifications.

In broad terms, we suggest that the following product categories be excluded from competitive bidding: diabetic shoes, diabetic inlays, prosthetics for the foot, and diabetic adjustments; fractures/sprain/injury related items, such as crutches, pneumatic walkers, other fracture ankle-foot orthoses (AFOs), items for ankle injuries, including braces and splints, and plantar fascia splints; AFOs, including non-pneumatic

walkers; and select wound care products, including negative pressure wound therapy (NPWT). If CMS prefers a more detailed list of suggested products for exclusion, we will be happy to comply. We are prepared to suggest items by HCPCS code if necessary and request that CMS contact us if more specific recommendations are required.

As we understand it, CMS believes that Therapeutic Shoes for Individuals with Diabetes (TSD) items are not subject to competitive bidding, although this is not specifically mentioned in the proposed rule. APMA strongly supports such exclusion. These items are provided for patients identified as being at risk and ensuring proper fit of TSD items is essential. If items are not fitted and used properly, complications could occur that might result in loss of limb or life. Since specific existing regulations apply regarding the certification of need, prescription and dispensing of those items, we believe that including them in competitive bidding would be counter-productive to patient care.

Additionally, we note that the proposed rule mentions in passing (in the impact analysis) that surgical dressings are not eligible for competitive bidding, and we support such exclusion as well. Many of the surgical dressings are used in wound care and must be available to patients undergoing treatment for acute or chronic wounds.

Specifically in relationship to the treatment of wounds, we believe that physician choice when determining appropriate wound care products is of paramount importance. Our members treat a wide variety of wounds, including diabetic ulcers. Our members save life and limb and contribute to the improvement of the quality of life and duration of life for Medicare beneficiaries, especially those with diabetes. There are a variety of challenges in providing wound care, not the least of which is that proper care can be costly, involve pain and suffering for patients, and interfere with the patient's activities of daily living and other normal activities.

We are concerned that physician choice and access to certain wound care products could be restricted as a result of the new competitive bidding process. An item of particular concern for our members is negative pressure wound therapy. In October 2000, a new HCPCS code, E2402, was established for NPWT and since 2003 more than 3,000 physicians have ordered NPWT more than 36,000 times.

In recent months, new products have been added to the E2402 code despite the fact that these new products are clinically different from the original NPWT product. Case studies involving the original NPWT product are attached for your review. As demonstrated, these products are used for wounds that are significant. In one of the case studies, the product is used post-amputation and after eight weeks of use, wound healing is evident. If this product were no longer available because only newer items described by HCPCS code E2402 are provided by contract suppliers, it is conceivable that wound healing could be compromised.

Since the category described by E2402 includes newer items that are not yet well understood or established and physician choice in selecting an item must be respected, we suggest that it is too risky to competitively bid that category at this time. Therefore, we recommend that NPWT products are not among those subject to the initial round of competitive bidding.

Finally, we note that, as mandated by the MMA, the proposed rule calls for subjecting only off-the-shelf orthotics (and not custom-made orthotics) to competitive bidding. APMA strongly supports the Congressional decision to exclude custom-made orthotics from the list of products eligible for competitive bidding.

Allow Physicians to Continue as Suppliers at the MSA Rate

Another option CMS could consider is to allow physicians and other qualified healthcare practitioners to continue to supply DMEPOS as they currently do provided they agree to supply the item at the single payment amount, the same rate that applies to the entire MSA. Since the proposed rule suggests establishing a single rate for each product subject to bidding in each MSA, the "bid" of the physician or other qualified healthcare practitioner would simply be a statement confirming their willingness to serve as a supplier and to supply items at the rate established by CMS. For physician-suppliers, we believe that such a bid could still be viewed as satisfying the statutory requirement that a bid specify "a particular price." In addition, since all or nearly all physician-suppliers are likely to easily satisfy any definition of "small supplier," our recommended approach for handling bids from physician-suppliers would help CMS respond to the statutory requirement that the Secretary "take appropriate steps to ensure that small suppliers…have the opportunity to be considered for participation in the [DMEPOS competitive acquisition] program."

This option would ensure that Medicare beneficiaries' access to patient care and to medically necessary and appropriate items is not negatively impacted as a result of the new program. They could continue to receive items from their physician or other qualified healthcare professional while still allowing CMS to achieve cost savings since the item would be provided at the CMS rate.

Physician Definition Should be Changed to 1861(r)

Based upon our June 21 meeting with CMS representatives, we understand that it is the agency's position that the *Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)* requires CMS to establish a competitive bidding program for all suppliers of DMEPOS. While we continue to believe that physicians and other qualified practitioners should be exempted from the requirement to competitively bid, it appears that CMS will proceed with competitive bidding for all suppliers. There are provisions within the proposed rule that will negatively impact a podiatric physician's ability to supply

medically necessary and appropriate DMEPOS to Medicare beneficiaries as an integral part of patient care.

The proposed definition of "physician" could lead some to conclude that podiatric physicians would not be allowed to participate in the new DMEPOS competitive bidding program. However, as we understand it, that was **not** CMS' intent. As noted earlier, more than 7,300 podiatric physicians currently have DMEPOS supplier numbers, and thus it seems rather doubtful that Congress would have intended to bar these individuals from continuing to serve as suppliers. In any case, the proposed definition of "physician" would appear to have other negative consequences for podiatric physicians and their patients. Since CMS did not recognize podiatrists as physicians for purposes of the proposed rule, podiatric physicians will not be able to bid to supply DMEPOS items to their patients only. Additionally, podiatric physicians will not have the ability to execute a physician authorization when they determine that a particular brand of item is necessary for the patient. We believe this decision will have serious consequences for our members and the Medicare beneficiaries they serve.

As noted earlier, in the proposed rule, CMS defined physician using the narrow 1861(r)(1) definition, which applies to MDs and DOs only. Since the prescribing, fabricating, fitting and dispensing of DMEPOS is within our scope of practice as defined by state law, this proposed action is in direct conflict with those laws as written.

We question why CMS selected this definition when our members provide DMEPOS items the same way that they are provided by MD and DO physicians. Our members perform a thorough evaluation of the patient prior to determining a course of treatment. As stated previously, our members prescribe and supply DMEPOS items as an integral part of patient care. They are required to obtain a valid supplier number and must adhere to the existing 21 supplier standards. They are licensed in the state in which they practice, are subject to the same Stark requirements that apply to MDs and DOs and must satisfy other Federal and State regulatory requirements. If a DMEPOS item is necessary, our members prescribe the item and if they have a valid supplier number, they may dispense that item in their office. Therefore, we urge CMS to revise the physician definition to 1861(r) so that all physicians recognized by Medicare are able to bid to supply items to their patients only and are able to execute a physician authorization. Additionally, we believe that other qualified healthcare practitioners should be able to supply DMEPOS that is used as an integral part of patient care.

We see nothing in the MMA that requires the proposed, narrow definition of "physician" for purposes of the DMEPOS competitive bidding program. We recognize that a separate provision, relating to the need for a face-to-face examination of a patient for coverage of certain DMEPOS, does limit the definition of physician to 1861(r)(1), but this provision is currently being applied only to power mobility devices and does not directly relate to the competitive bidding program.

In sum, we urge CMS to modify the definition used for physicians who may bid to supply DMEPOS to their patients only and who may execute a physician authorization from 1861(r)(1) to 1861(r).

Criteria for Item Selection

We realize that CMS has yet to identify the specific products or product categories that will initially be subject to bidding. We suggest that care be exercised in establishing the product categories for the future. Scope of practice limitations exist for our members and it would not make sense to require podiatric physicians to, for example, competitively bid to supply all off-the-shelf orthotics. Our members supply lower extremity orthotics and would be unable to supply upper extremity orthotics. Other specialties could be similarly challenged. For instance, it is unlikely that orthopedic hand surgeons would supply lower extremity orthotics. When establishing product categories, we urge CMS to be realistic and avoid making the categories so broad that it actually prevents some specialties from bidding.

Quality Standards and Accreditation for Suppliers of DMEPOS

The APMA is concerned with the application of quality standards, as well as the establishment of an accreditation process, for all suppliers of DMEPOS. Specifically, if a uniform set of standards and a single accreditation process are utilized, it is conceivable that the standards and process could be so onerous or expensive that physician suppliers would be unable or unwilling to serve as DMEPOS suppliers. As a result, patient care could suffer.

While we recognize that the proposed rule was limited in its discussion of the quality standards and accreditation process, and we expect the release of the final quality standards in the near future, we believe physicians should have a unique set of quality standards and a separate accreditation process. At the very least, we object to a uniform set of standards and a single accreditation process for all suppliers of DMEPOS. We believe that the standards and accreditation process should be fair and reasonable and should be reflective of the amount of DMEPOS supplied to Medicare beneficiaries.

Podiatric and other physicians must obviously meet state licensing requirements, and subjecting them to additional or potentially duplicative requirements could be overly and unnecessarily burdensome. We believe that it is reasonable to utilize a process for physician suppliers that differs from the one used for traditional suppliers lacking professional licensure. To subject a licensed physician, who might supply $5,000 worth of DMEPOS to Medicare beneficiaries over the course of a year to the same standards and accreditation process that apply to an entity supplying $1,000,000 worth of DMEPOS seems unreasonable. We encourage CMS to be reasonable in establishing quality standards and an accreditation process for physician suppliers.

Additionally, if the costs associated with becoming accredited (including the fee paid to the accreditation organization) are excessive when compared to the amount of DMEPOS supplied, or the process is overly burdensome, physicians may decide against functioning as DMEPOS suppliers. Patient access and patient care could be compromised.

If accreditation is required for all suppliers, physicians must have equal and appropriate access to the accrediting organizations. A single accrediting body for podiatric physicians who supply DMEPOS does not exist. Since accreditation by suppliers will be required before the program starts, our members would be disadvantaged. Other physicians and qualified healthcare practitioners would likely face similar challenges. We believe that if CMS intends to require an accreditation process for physicians beyond state licensing, the agency must ensure that a reasonable and fair pathway exists for physicians and other qualified healthcare professionals who wish to become accredited. The details of the accreditation process should be immediately communicated so that physicians and other qualified healthcare practitioners who wish to serve as suppliers in the new competitive bidding program understand the process they must follow.

Conclusion

The APMA appreciates the opportunity to offer these comments. The competitive bidding program, as proposed, is of significant concern to our members and we are hopeful that CMS will revise its proposals prior to issuing final regulations. If you have questions or require additional details, please contact Dr. Nancy L. Parsley, Director of Health Policy and Practice, at (301) 581-9233.

Sincerely,

David M. Schofield, DPM
President

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September 28, 2007

Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS–6006–P
P.O. Box 8017, Baltimore, MD 21244–8017.

RE: CMS–6006–P
Medicare Program; Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies
(72 Fed. Reg. 42001, Aug. 1, 2007)

Comments submitted electronically at http://www.cms.hhs.gov/eRulemaking

Dear Mr. Weems:

The American Podiatric Medical Association (APMA), the national association representing more than 11,500 of America's premier foot and ankle physicians and surgeons, is pleased to comment on the proposed rule that would require Medicare suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) to obtain a surety bond.

PROVISIONS

The proposed rule would require all DMEPOS suppliers to obtain a surety bond. However, the Centers for Medicare & Medicaid Services (CMS) invited comments on the need for exemptions for various types of suppliers, including physicians and non-physician practitioners. The APMA believes very strongly that any surety bond requirement should not apply to physicians, including podiatric physicians, even in their role as DMEPOS suppliers. We have two compelling reasons physicians (defined in Section 1861(r) of the Social Security Act) should be exempt.

First, the APMA believes that the Congress did not intend surety bond requirements to apply to physicians, including podiatric physicians. We note, for example, that the conference report language accompanying the Balanced Budget Act of 1997 (BBA) includes the following expression of Congressional intent:

> "The conferees wish to clarify that these surety bond requirements do not apply to physicians and other health care professionals" [emphasis added].

Please note that the above excerpt from the conference report explicitly refers to surety bond requirements in the plural, which we believe is an indication that the Congress did not intend any of the surety bond requirements specified in section 4312 of the BBA to apply to physicians or non-physician practitioners. In addition to looking at the conference report, we believe that Congressional intent can be found in the statute itself. Section 4312(c) of the BBA, which provides authority for the Secretary to apply surety bond requirements to health care providers other than

suppliers of durable medical equipment, explicitly states that any such extension may not apply to "physicians or other practitioners, as defined in section 1842(b)(18)(C)…" We assume that it is this specific section of the BBA that is being relied upon by CMS in proposing surety bond requirements for suppliers of prosthetics, prosthetic devices, and orthotics. In making this assumption, we note that section 4312(a) of the BBA only refers to suppliers of durable medical equipment, not prosthetics, prosthetic devices or orthotics. In the past, the Congress has been explicit when it wished specific requirements to apply to all suppliers of DMEPOS, not just suppliers of durable medical equipment. For example, when Congress mandated new quality standards for DMEPOS suppliers (at section 1834(a)(20) of the Social Security Act), it explicitly enumerated the items and services to be covered by such standards to include not only durable medical equipment, but "prosthetic devices and orthotics and prosthetics." Moreover, we assume that specific reference to the phrase "excluding physician and other practitioners as defined in section 1842(b)(18)(C) of the Act" in the impact analysis accompanying the proposed rule (see page 42008 of the August 1, 2007 *Federal Register*, first column bottom) is an allusion to the language in section 4312(c) of the BBA, suggesting CMS recognition that the Congress had expressed a view with respect to the exemption of such practitioners from surety bond requirements.

Taken together, then, we believe that the conference report and statutory excerpts mentioned above provide considerable evidence that the Congress intended to exempt physicians, including podiatric physicians, from any surety bond requirements. We note, too, that there appears to be no similar expression of Congressional intent, vague or otherwise, with respect to large publicly traded suppliers, rural DMEPOS suppliers or the other categories of suppliers for which CMS has invited comments about possible exemptions.

Second, and more important than any legal consideration, the APMA believes that the application of surety bond requirements to physicians and other practitioners will seriously compromise Medicare beneficiary access to high quality care. In the case of physicians, including podiatric physicians, DMEPOS products are provided as an integral part of patient care. Further, in the case of physicians, DMEPOS products typically make up only a relatively small proportion of the total items and services routinely provided to Medicare beneficiaries. CMS itself projects that the proposed surety bond requirements will cause many if not all DMEPOS suppliers who now provide relatively small quantities of DMEPOS to Medicare beneficiaries to cease doing so, and the APMA believes that many such suppliers will be physicians. As noted by CMS in the proposed rule, physicians, including podiatric physicians, cannot incur the cost of a surety bond if there is little or no likelihood that this cost will be covered in the course of furnishing DMEPOS products to their Medicare patients. If the projected exodus of DMEPOS suppliers occurs, then what would happen to the Medicare beneficiary who presents to a physician's office with a problem or condition for which a specific item of DMEPOS would be of immediate benefit?

To consider this question further, we believe it would be useful to focus on some common clinical situations in podiatric medical practice. According to CMS, there are more than 7,300 podiatric physicians who are DMEPOS suppliers. Examples of how podiatric physicians utilize DMEPOS in patient care include the following:

- A patient presents complaining of foot pain and swelling after tripping on a sidewalk. The podiatric physician diagnoses multiple fractures of the metatarsals and determines that a Cam walker is necessary for immobilization of the injured foot. If that podiatrist no longer functions as a supplier, the patient will be forced to travel to another location to obtain the brace, treatment will be delayed or perhaps never implemented, and the patient will risk further injury to the foot.

- A podiatric physician may treat a patient with an acute ankle injury and determine that an ankle brace is necessary to stabilize the ankle and that crutches are necessary to limit weight-bearing on the injured extremity. If that podiatric physician is not a DMEPOS supplier because being so is no longer practical as a result of surety bond requirements, the patient will need to go elsewhere to obtain the medically necessary items. The patient risks converting the existing injury into one that is more severe, with greater recovery time and increased risks for complications.

As should be obvious from the preceding examples, patients with conditions requiring acute care (e.g., fractures, foot or ankle injuries), must have immediate access to appropriate treatment, including DMEPOS items such as pneumatic walkers, non-pneumatic walkers, ankle braces, crutches, canes and walkers. These items need to be sized and fitted by the doctor. The patient needs to be instructed on proper use of the item, including weight-bearing activities. A delay in care could put the patient at risk for additional injury, which could result in increased costs to the Medicare program for the care of that patient. The physician might also need to supply an item at the point of service to meet the applicable standard of care. For instance, if the patient with the foot fracture falls because she is unable to bear full weight on the injured extremity and breaks her hip as well, additional expenses will be incurred by the Medicare program and the physician might face additional liability. Or, a delay in receipt of necessary DMEPOS items could result in the deterioration of the patient's medical condition. A stable fracture could become unstable, thereby increasing the severity of the existing injury. A fracture that could initially be treated with a closed reduction could require an open reduction, which would increase costs to the Medicare program. At the very least, a delay in treatment could lead to increased, prolonged disability or less than desired results that may have a permanent impact on the activities of daily living (ADLs) of the patient.

Even for non-acute cases, the clinical judgment and expertise of the physician remain essential. The selection of a particular item of DMEPOS, as well as its size and fit, should be based on the physician's evaluation of the patient. Instruction on the proper application or use of the item is important. The physician dispenses the item based on the pathology of the patient and can best explain why the item is necessary and how it must be used. The physician is able to check the fit of the item and can determine if the patient will be able to use it successfully. A different item may be needed than the one originally prescribed and the physician is the best person to make this determination. If difficulty in using an item is not immediately identified by the physician and the patient receives it from a separate supplier and the fit is incorrect, the patient may ultimately not use the item or may use it improperly, all of which could contribute to the deterioration of the patient's condition and lead to increased costs to the Medicare program. Or, some patients may return to the

physician's office with questions or for assistance, which would also increase costs due to the need for additional care or instruction.

In addition to clinical considerations, there are also obvious differences in the quantities of DMEPOS products provided by physicians compared to the amounts provided by suppliers who do nothing but furnish DMEPOS products. According to 2004 Medicare data on DMEPOS services, practitioners were responsible for 3.1 percent of DMEPOS allowed charges while entities categorized as "suppliers" were responsible for 96.4 percent of those charges. Most podiatric physicians, who operate as small businesses, supply limited quantities of DMEPOS items to Medicare beneficiaries as part of quality, appropriate, and necessary patient care. Requiring physicians to obtain surety bonds to continue to supply DMEPOS to patients at the point of service will disrupt Medicare beneficiaries' access to care that is in their best interest.

The APMA believes that access and quality of care considerations, and known differences in the quantities of DMEPOS products provided by physicians and DMEPOS-only suppliers, were among the factors that led the Congress to conclude (as discussed earlier in these comments) that surety bond requirements should not be applied to physicians.

In sum, the APMA urges CMS to exempt all physicians, including podiatric physicians, from the proposed DMEPOS supplier surety bond requirements when these individuals are furnishing DMEPOS as an integral part of the care provided to their own patients.

In addition to obtaining an exemption for physicians, which is the APMA's principal concern, we wish to take this opportunity to offer the following, three additional comments:

- First, if CMS concludes that there are good policy reasons for exempting certain categories of DMEPOS suppliers from any surety bond requirements (in addition to exempting physicians) the APMA recommends that CMS defer publication of a final rule until explicit Congressional guidance on this can be obtained. Similarly, if CMS remains uncertain about Congressional intent with respect to the exemption of physicians, despite the evidence reviewed above, we again recommend deferring publication of a final rule until this matter can be resolved by the Congress. Since 10 years have now passed since enactment of the BBA surety bond provision, there seems to be no particular urgency to publishing a final rule at this time.

- Second, if and when CMS imposes a surety bond requirement on any DMEPOS suppliers, the APMA recommends that the requirement be applied at the tax identification number (TIN) or similar level of aggregation, and not at the national provider identifier (NPI) level. A supplier with several locations or with more than one NPI (for whatever the reason) should not be expected to submit more than one surety bond.

- Finally, if and when CMS imposes a surety bond requirement on any DMEPOS suppliers, the APMA recommends that the agency give the affected suppliers at least 6 months, not 60

days, to comply. Providing an unduly short amount of time to comply seems especially unnecessary and ill-advised when the authorizing statute was enacted a full 10 years ago.

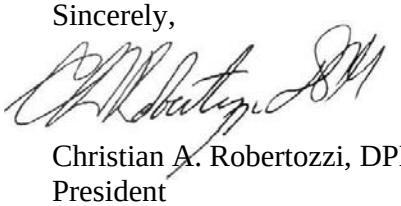
IMPACT

The proposed rule provides a confusing array of data with respect to the number of DMEPOS suppliers that would be affected. For example, in the impact analysis, in estimating the costs of obtaining surety bonds, CMS assumes that "approximately 99,000" suppliers will be involved (and that the average annual cost of a bond will be $2,000). However, in the section of the proposed rule summarizing collection of information requirements, CMS estimates that "approximately 116,500 DMEPOS suppliers" will comply with the proposed surety bond requirements. Any final rule should make sense of the conflicting array of data.

More importantly, CMS predicts that almost all of the nearly 16,000 billing suppliers with allowed charges of less than $1,000 in fiscal year 2005 will drop out of Medicare. CMS also predicts that the majority of the 14,000 with allowed charges between $1000 and $5,000 will also drop out. To be more precise, CMS projects that "as many as 15,000 DMEPOS suppliers, or 23 percent of the 65,984 entities, and 15 percent (or 17,471) of the 116,471 individual suppliers currently enrolled in Medicare could decide to cease providing items to Medicare beneficiaries if this proposed rule is implemented." CMS also believes that "approximately 22 percent of the 15,000 DMEPOS suppliers are located in rural areas." The APMA believes that all of these projections should be cause for alarm, not support for implementing a final rule as proposed. A significant reduction in the number of DMEPOS suppliers will almost certainly have negative consequences for Medicare beneficiary access to DMEPOS, especially in rural areas. We cannot believe that this is what the Congress intended. In our view, CMS's estimated impact provides yet another rationale for deferring adoption of a final rule and for undertaking fresh consultations with the Congress now that a decade has passed since the BBA was enacted.

We hope the above comments are helpful. If you have any questions about them or need additional information from the APMA, please contact Rodney Peele, APMA's Assistant Director of Health Policy and Practice, at 301-571-9200 or via e-mail at RDPeele@apma.org.

Sincerely,



Christian A. Robertozzi, DPM
President